

Remarks/Arguments

Claims 1, 3-16, 8-9, 12-14, 17, and 81-94 are pending in the application. Claims 17 and 83 appear for the Examiner's review and reconsideration. Claims 1, 3-16, 8-9, 12-14, 81-82, and 84-94 stand withdrawn as drawn to non-elected subject matter.

It is respectfully requested that the Examiner contact the undersigned for an interview.

Election/Restrictions:

The Office Action states that restriction to one of eight groups of invention is required under 35 U.S.C. § 121.

The Applicants confirm the provisional election of Group IV (claims 17 and 83), with traverse, made by the undersigned during a telephone conversation with the Examiner on October 26, 2006.

Applicants expressly reserve the right to file a divisional application encompassing the claims of non-elected Groups I-III and V-VIII prior to issuance of this application. Further, Applicants expressly reserve the right to rejoin the claims of the non-elected Groups upon allowance of one or more of the claims of elected Group IV.

This election is made with traverse because it is believed that the claims can be regrouped into a single group.

As the Examiner is aware, there are two criteria for a restriction requirement: (A) the inventions must be independent or distinct as claimed; AND (B) there must be a serious burden on the Examiner. "If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct invention." M.P.E.P. § 803 (August 2006).

Applicants believe that examining all of the pending claims as a single group would not place an undue burden on the Examiner to search using the PTO's classification system since all the claims of the application are directed to amorphous valsartan or processes for preparing the amorphous valsartan. All the claims in the suggested group are sufficiently similar to make it possible to examine these claims without serious burden, with minimal search, and extensive overlap of art. The art relevant for claims to amorphous valsartan is likely to be highly relevant for claims to processes for preparing the amorphous valsartan. Accordingly, the Applicants believe that regrouping the claims into a single group would expedite prosecution of the present case.

Claim Rejections – 35 U.S.C. §§ 102, 103:

The Office Action rejects the claims under Section 102 and 103 in light of U.S. patent No. 5,399,578 to Buhlmayer et al. (“Buhlmayer”) The melting range provided in Buhlmayer for the product of Example 16 is 105-115°C.

The fact that Buhlmayer provides a melting range for its product means that its product is not purely amorphous. Certain materials, such as glass, may harden without crystallizing; these are called amorphous solids. Amorphous materials as well as some polymers do not have a true melting point as there is no abrupt phase change at any specific temperature. Instead, there is a gradual change in their viscoelastic properties over a range of temperatures. Such materials are characterized by a glass transition temperature which may be roughly defined as the "knee" point of the material's density vs. temperature graph. As such, Buhlmayer cannot anticipate under Section 102 the claims of the present invention directed to pure amorphous form.

Neither does Buhlmayer render the claims of the present invention obvious. Buhlmayer does not teach or suggest pure amorphous form as claimed, nor does it provide an enabling process for preparation of such amorphous form. As such it cannot render the subject matter of the present claims obvious.

Claim Rejections – 35 U.S.C. §112:

Claims 17 and 83 have been rejected under Section 112, second paragraph for reciting the term “above about.” The definiteness requirement of Section 112 is satisfied when “the claims at issue [are] sufficiently precise to permit a potential competitor to determine whether or not he is infringing.” *Morton Int’l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). In this case a competitor would understand that the claims cover amounts above a certain recited number. The Examiner has not cited any legal basis for the proposition that a claim which lacks an upper limit is indefinite.

Claims 17 and 83 have also been rejected under Section 112, second paragraph for not standing alone. The Applicants disagree because these claims are complete in themselves. There is no prohibition in citing DSC characteristics in a claim. The figures do not even reference a figure.

Claims 17 and 83 have also been rejected under Section 112, second paragraph for not reciting "purely amorphous" or "essentially amorphous." It is respectfully submitted that the claims by reciting specific DSC characteristics permit a potential competitor to determine whether or not he is infringing. All a competitor has to do is to subject its product to DSC analysis.

Conclusion:

Having addressed all the outstanding rejections and objections, Applicants submit that the application is in a condition for allowance. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon LLP, Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON LLP

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